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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,555	03/11/2005	Max Werner Scheiwe	753-47 PCT/US	5860
<div>23869 7590 10/31/2007</div> <div>HOFFMANN & BARON, LLP</div> <div>6900 JERICHO TURNPIKE</div> <div>SYOSSET, NY 11791</div>				
			<div>EXAMINER</div> <div>SIMMONS, CHRIS E</div>	
			<div>ART UNIT</div> <div>1614</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>10/31/2007</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,555	Applicant(s) SCHEIWE ET AL.	
	Examiner Chris E. Simmons	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 10, 19 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Status of the claims: Applicant's election without traverse of Group 1 (claims 1-18) and elected species pirfenidone as the active agent, caprylic/capric triglyceride as the triglyceride, and maize oil as the solvent in the reply filed on 08/31/2007 is acknowledged.

Claims 10, 19 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or specie, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08/31/2007. Applicant canceled claim 20 in a prior response. Claims 1-9 and 11-18 are, therefore, examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-6 and 13-15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board

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of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 3-6 recite broad ranges of amounts of ingredients, and the claims also recites "preferably" followed by narrower ranges.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-9 and 11-18 are rejected under 35 USC 103(a) as being unpatentable over WO0016775 ('775) in view of Jumaa et al. ("Parental emulsions stabilized with a mixture of phospholipids and PEG-660-12-hydroxystearate: evaluation of accelerated and long-term stability"; European Journal of Pharmaceutics and Biopharmaceutics; 54; 2002:207-212.), US 4,931,285 ('285) and STN REGISTRY DATA for Miglyol 812 (1984).

Determination of the scope and content of the prior art (MPEP 2141.01)

'775 generally discloses a pharmaceutically acceptable topical formulation comprising pyridone together with an excipient, characterized in that the excipient comprises one or more plasticizers, one or more antioxidants, one or more gel-forming agents and a pH adjusting agent (page 3, last paragraph). Preferable excipients present in the compositions of the reference are listed at pages 4-6. Specifically, '755 discloses a topical preparation comprising pirfinedone (5% wt. active agent), polypropylene glycol (5% wt. penetration enhancer, which is interchangeable with

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propylene glycol (i.e., propanediol), page 4, second paragraph), oleic acid decylester (5% wt. superfatting agent), medium-chain triglycerides (10% wt.), stearic acid (5% wt. consistency regulator), cetyl stearyl alcohol (5% wt. emulsifier), sodium methylparaben (0.2% wt. preservative), sodium propylparaben (0.2% wt. preservative), and water (page 8, 'Comparative Example 2'). '755 discloses in the preferred antioxidant is sodium metabisulfite (page 4, third paragraph).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

'775 does not expressly disclose macrogol 15 HS (i.e., surface-active solubilizer) the elected solvent (i.e., maize oil), and the elected medium-chain triglyceride (i.e., caprylic/capric triglyceride) as ingredients in the disclosed preparation.

Finding of prima facie obviousness

Jumaa et al. discloses how to make stable emulsion preparations comprising Miglyol 815 (i.e., caprylic/capric triglyceride – see accompanying STN REGISTRY DATA for Miglyol 812) and Solutol 15 HS (i.e., macrogol 15 HS) (abstract; page 208, paragraph under '2.1 Materials').

'775 and Jumaa et al. are analogous art because they are from a similar problem solving area viz preparing stable emulsion preparations .

At the time of the invention it would have been obvious to a person of ordinary skill in the art to make the claimed invention by picking and choosing well known excipients commonly used in topical preparations.

Comparative Example 2 recited in '775 combined with Jumaa et al. discloses the limitations of claims 1-17, which are generic to claim 18.

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As for the solvent, maize oil (i.e., corn oil), '775 discloses that one or more plasticizers may be components in the compositions. Examples of plasticizers (e.g., mineral oil, etc) are listed at page 4, second paragraph. '285 discloses mineral oil and corn oil as a commonly interchangeably used plasticizers in cosmetic preparations (col. 5, lines 21-22, 61, and 65).

As for the amount limitations of each ingredient, it is not patentable to optimize the concentration of each ingredient of a composition through routine experimentation. Differences in concentration from what is disclosed in the references, will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. It is not inventive to discover the optimum or workable ranges by routine experimentation. (See MPEP 2144.05 [R-5] II A).

Rational and Motivation (MPEP 2142-2143)

The suggestion/motivation for doing so would have been to make a topical emulsion composition that is stable ('755, page 2, last 2 sentences of the first paragraph; Jumaa et al., page 211, *Conclusion*). As such, a prima facie case of obviousness of the claimed limitations of claims 1-9 and 11-18 over the above references is clearly made by the Examiner.

Therefore, it would have been obvious to combine the teachings in each reference to obtain the invention as specified in claim.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re*

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Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

For reasons set forth above, Claims 1-9 and 11-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, and 7-20 of U.S. Patent No. 6,492,395 in view of Jumaa et al. ("Parental emulsions stabilized with a mixture of phospholipids and PEG-660-12-hydroxystearate: evaluation of accelerated and long-term stability"; European Journal of Pharmaceutics and Biopharmaceutics; 54;2002:207-212.), US 4,931,285 ('285) and STN REGISTRY DATA for Miglyol 812 (1984).

'395 claims a composition comprising a pyridone, (e.g., pirfenidone; column 2, line 32) and an excipient composition comprising at least 1 plasticizer (e.g., polypropylene glycol, mineral oil, etc.) at least 1 antioxidant (e.g., sodium metabisulfite), at least 1 gel-forming agent, emulsifier (e.g., cetostearyl alcohol, stearic acid, etc.; column 3, lines 2 and 10) and water. '395 further discloses a composition comprising other possible excipients that are encompassed by the instant claims. Comparative Example 2 discloses an ointment comprising an active ingredient with excipients: pirfenidone (5% wt. active agent), polypropylene glycol (5% wt. penetration enhancer), oleic acid decylester (5% wt. superfatting agent), medium-chain triglycerides (10% wt.), stearic acid (5% wt. consistency regulator), cetyl stearyl alcohol (5% wt. emulsifier), sodium methylparaben (0.2% wt. preservative), sodium propylparaben (0.2% wt. preservative), and water (column 4, 'Comparative Example 2').

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

'395 does not expressly disclose macrogol 15 HS (i.e., surface-active solubilizer) the elected solvent (i.e., maize oil), and the elected medium-chain triglyceride (i.e., caprylic/capric triglyceride) as ingredients in the disclosed preparation.

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Finding of prima facie obviousness

Jumaa et al. discloses how to make stable emulsion preparations comprising Miglyol 815 (i.e., caprylic/capric triglyceride – see accompanying STN REGISTRY DATA for Miglyol 812) and Solutol 15 HS (i.e., macrogol 15 HS) (abstract; page 208, paragraph under '2.1 Materials').

'395 and Jumaa et al. are analogous art because they are from a similar problem solving area viz preparing stable emulsion preparations .

At the time of the invention it would have been obvious to a person of ordinary skill in the art to make the claimed invention by picking and choosing well known excipients commonly used in topical preparations.

Comparative Example 2 recited in '395 combined with Jumaa et al. discloses the limitations of claims 1-17, which are generic to claim 18.

As for the solvent, maize oil (i.e., corn oil), '395 discloses that one or more plasticizers may be components in the compositions. Examples of plasticizers (e.g., mineral oil, etc) are listed at page 4, second paragraph. '285 discloses mineral oil and corn oil as a commonly interchangeably used plasticizers in cosmetic preparations (col. 5, lines 21-22, 61, and 65).

As for the amount limitations of each ingredient, it is not patentable to optimize the concentration of each ingredient of a composition through routine experimentation. Differences in concentration from what is disclosed in the references, will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. It is not inventive to discover the optimum or

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workable ranges by routine experimentation. (See MPEP 2144.05 [R-5] II A).

Rational and Motivation (MPEP 2142-2143)

The suggestion/motivation for doing so would have been to make a topical emulsion composition that is stable ('395, column 1, lines 39-43; Jumaa et al., page 211, *Conclusion*). As such, a *prima facie* case of obviousness of the claimed limitations of claims 1-9 and 11-18 over the above references is clearly made by the Examiner.

Therefore, it would have been obvious to combine the teachings in each reference to obtain the invention as specified in claim.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

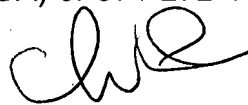
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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris E. Simmons whose telephone number is (571) 272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Chris Simmons
Patent Examiner
AU 1614

October 23, 2007



ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER